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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,433	02/27/2004	Mark Thomas Muldoon	19596-0571 (45738-296417)	5696

23370 7590 08/28/2008

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
08/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,433	MULDOON ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *10-13,15-17 and 20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *10-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed June 5, 2008 has been entered. Claims 10 and 20 have been amended. Claims 1-9, 14 and 18-19 are cancelled.

Election/Restrictions

2. Applicant's election with traverse of claim 20 in the reply filed on June 5, 2008 is acknowledged. The traversal is on the ground(s) that duplicate sequences are recited in claims 10 and 20, therefore claim 20 should not be withdrawn from consideration. This is not found persuasive because claim 20 does not recite elected sequence, SEQ ID NO:2. Claim 20 is drawn to an invention that is independent or distinct because SEQ ID NO: 3-6, 9-13 and 15-35 do not share physical and functional characteristics with elected SEQ ID NO:2. The amino acid sequences constitute patentably distinct inventions which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each sequence comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Furthermore, it is noted that applicants are not traversing on the ground that the inventions are patentably distinct. Therefore applicants' statements are not persuasive. Neither has applicant submitted evidence showing that the sequences are obvious variants of each other nor has applicants clearly admit on the record that the sequences are obvious variants of each other.

Therefore applicants argument is not persuasive, thus requirement is still deemed proper and is therefore made FINAL.

Since applicant has received an action on the merits for the originally presented invention drawn to claims having SEQ ID NO:2, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 20 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 10-13 and 15-17 and SEQ ID NO:2 are under consideration in this office action.

Withdrawal of Rejections

4. The enablement rejection of claims 10-13 and 15-17 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of applicants amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The new matter rejection of claims 10-13 and 15-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The rejection is on the grounds that Neither the specification nor originally presented claims provides support for reacting the animal feed with a ligand wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequences consisting of SEQ ID NO:2. Applicant did not point to support in the specification for reacting the animal feed extract with a ligand wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequences consisting of SEQ ID NO:2. Moreover, applicant failed to specifically point to a ligand wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequences consisting of SEQ ID NO:2. Thus, there appears to be no teaching of an assay for detecting a mammalian troponin molecule in animal feed as claimed.

Response to Arguments

6. Applicant's arguments filed June 5, 2008 have been fully considered but they are not persuasive.

Applicants argue that the claims are clarified because the claims recite that the mammalian troponin molecule is extracted from animal feed to form an animal feed extract prior to reacting the animal feed with a ligand. Applicants point to Example 1 which is drawn to extracting proteins from the sample using well known methods. However, there is no teaching of reacting the animal feed extract with a ligand wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequences consisting of SEQ ID NO:2. Page 20 recites the use of diluted

feed stock extract containing mammalian troponin protein, however there dies not provide support for a ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequences consisting of SEQ ID NO:2.

Thus it appears that the entire specification appears to fail to recite support for the recited step within the assay. Therefore, it appears that there is no support in the specification. Applicants must specifically point to page and line number support for an assay for detecting a mammalian troponin molecule in animal feed the assay comprising: a) extracting the mammalian troponin molecule from the animal feed to form an animal feed extract; b) reacting the animal feed extract with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and c) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Therefore, applicants arguments are not persuasive and the rejection is maintained.

New Grounds of Rejections Necessitated By Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 10, step (c) recites measuring the presence or amount of the troponin molecule in the animal feed, however it is unclear how the presence or amount of the troponin molecule in the animal feed can occur since it is the extract that is reacted with the ligand and not the animal feed itself. Therefore clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) in view of Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

Claim 10 is drawn to an assay for detecting a mammalian troponin molecule in animal feed, the assay comprising: a) extracting the mammalian troponin molecule from the animal feed to form an animal feed extract; b) reacting the animal feed extract with a

ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin molecule; and c) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed and wherein the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2. Claim 11 is drawn to the mammalian troponin molecule is a troponin I molecule. Claim 12 is drawn to the mammalian troponin molecule is a troponin I molecule is selected from the group consisting of a slow twitch skeletal muscle troponin I molecule and a fast twitch skeletal muscle troponin I molecule. Claim 13 is drawn to the ligand being an antibody and the troponin molecule is a polypeptide. Claim 15 is drawn to the ligand binds to a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 16 is drawn to the ligand binds to a nucleic acid molecule encoding a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. Claim 17 is drawn the ligand is specific for an equine troponin I protein, a porcine troponin I protein or a bovine troponin I protein.

Chen et al., teach immunological methods for detecting the porcine troponin I wherein immunoblotting was performed using isolated proteins detected by a monoclonal antibody (page 56, col.2). Chen et al., teach an indirect ELISA using the monoclonal antibody as the detection reagent for detecting porcine skeletal troponin I (sTnI) (page 57, col.1). Figure 2 shows the result of detecting porcine sTnI in a sample for a time and under conditions sufficient to form a complex between the ligand and the troponin; and indirectly detecting the complex as a measure of the presence or amount

of the troponin molecule in the sample. Chen et al., teach the specificity of the monoclonal antibody which recognized porcine sTnI but not other troponin molecules from chicken (page 58, col.2). Chen et al., teach the production of monoclonal antibodies from immunized mice (page 56, col.2). The samples were raw and cooked porcine muscle extracts (page 56, col. 1-2) to thereby form the animal feed extract. It is noted that the specification at page 5, lines 6-11 teach that the term "animal feed" refers to any substance provided to an animal for nourishment, including preparations from meat products from animals for human consumption. Therefore the use of raw and cooked porcine muscle samples, meets the limitation drawn to animal feed and animal feed extract.

Chen et al., teach that several specific monoclonal antibodies have been raised to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of bovine, porcine and chicken adulteration in meat mixtures (page 55, col.1). Chen et al., teach it is important to reveal the identity and specific antigenicity of the skeletal muscle troponin from several other species for the development of species-specific antibodies (page 55, col.2). Chen et al., teach the recognition and use of monoclonal antibodies as specific for sTnI and demonstrated the heterogeneity of sTnI is differentiated immunologically with antibodies at the species level (page 56, col.1). Chen et al., teach sTnI is an ideal species marker for immunoassays for the detection of species origins in the meats of severely heat-processed commodities (page 60, col.1). However Chen et al., do not explicitly teach a ligand that reacts with or binds to SEQ ID NO:2.

Sheng et al., teach assay for detecting a mammalian rabbit skeletal muscle the polypeptide or cDNA troponin I (TnI) molecule in a lysate sample, by western blotting whereby the sample contains a skeletal monoclonal antibody ligand specific for troponin

I having SEQ ID NO:2 to form a complex between the antibody and troponin I; and detecting the complex as a measure of the presence of the troponin I (Figure 3). In Figure 3, Sheng et al., show an immunoblot result and detection of TnI with a monoclonal antibody. Sheng et al., teach rabbit skeletal muscle cDNA clone for troponin I and encoding rabbit fast twitch skeletal muscle TnI (page 25, 408, col.1). Sheng et al., teach the cDNA and the deduced amino acid sequence of rabbit fast skeletal muscle TnI in Figure 1 and the nucleotide sequence homology of rabbit and mouse TnI in Figure 2. Sheng et al., teach monoclonal antibodies that react with or binds to SEQ ID NO:2. Furthermore Sheng et al., teach the production of the TnI monoclonal antibody which include a monoclonal antibody produced by immunizing an animal with the peptide having SEQ ID NO:2 (page 25,409, col. 2). Sheng et al., also teach a ligand that binds to SEQ ID NO:2; and a ligand that binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2.

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the ligand reacts with or binds to an amino acid sequence selected from the group consisting of SEQ ID NO:2 of Sheng et al, to the assay for detecting a mammalian troponin molecule in a sample as taught by Chen et al., in order to provide a consistent and continuous supply of immunoreagents for routine immunoassays for the detection of species adulteration. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the monoclonal antibody ligand of Chen et al., for the monoclonal antibody ligand of Sheng et al., which reacts with and/or binds to SEQ ID NO:2 because Chen et al., teach the desire to have specific troponin species marker for detection immunoassays. Furthermore, no more than routine skill would have been required to exchange the ligand of Chen et al., for the available ligand of Sheng et al., since Chen et al., teach the desire to have a variety of mammalian

troponin ligands, like the ligand of Sheng et al., that selectively bind SEQ ID NO:2 or rabbit troponin and have the ability to not be specific for avian troponin molecules. Finally it would have been prima facie obvious to combine the invention of Chen et al., and Sheng et al., to advantageously achieve the detection of mammalian troponin in adulterated meat samples since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

9. No claims allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645